

### Remarks

Claims 1-26, 31-40, 44 and 45 are pending in the application. The subject matter of claim 43 has been combined into claim 40. Claim 43 has been cancelled. Claims 41-42 have likewise been cancelled in view of the amendment to claim 40.

Claim 35 has been amended to correct an inadvertent error in dependency. Claim 35 recites a method for producing a polypeptide, including the step of preparing an expression vector for the polypeptide to be produced by cloning the coding sequence for the polypeptide into the cloning site of an expression construct *as claimed in claim 30*. Claim 30 is a “use” claim. The antecedent for the expression construct referenced in claim 35 is found not in claim 30, but claim 31. Thus, the dependency of claim 35 has been amended to depend from claim 31. Applicants regret the error.

Claims 27-30, directed to claims in the “use” format, have been cancelled.

Claim 44 is new. Claim 44 is based on the combination of claims 1, 2 and 10, insofar as the claimed method utilizes a vector capable of encoding a fusion protein with the solubility enhancing tag SNUT.

Claim 45 is new. Claim 45 is based on the combination of claims 20 and 23, insofar as the claimed method utilizes a vector capable of encoding a fusion protein with the solubility enhancing tag SNUT.

Claim 26 has been amended to depend from new claim 44.

The amendment and cancellation of claims herein is without prejudice to the filing of continuing applications.

### Restriction and Election of Invention

Restriction has been required from among four groups of claims identified in the office action. Applicants elect the claims of Group IV, now constituting claims 35-40, as well as new claims 44 and 45. The election is made with traverse, for the reasons set forth below. Applicants reserve the right to request rejoinder of any non-elected claim pursuant to MPEP 821.04.

New claims 44 and 45 incorporate the use of a sortase gene product as a purification tag. Hence, they should be grouped with Group IV, the elected group.

#### Traversal of Restriction

Applicants respectfully traverse the finding of lack of unity as it applies to Groups II, III and IV. Examiner alleges that the claims of the application do not relate to a single general inventive concept under PCT Rule 13.1, because under PCT Rule 13.2, they allegedly lack the same or corresponding technical feature. Examiner alleges that Graham-Siegenthaler *et al.* and Pat. 5,804,408 disclose a composition comprising HPMA conjugated to a polyamine, thereby allegedly teaching a technical feature linking the claims. Applicants respectfully disagree.

Each of claim Groups II, III and IV, share the same special technical feature, i.e., the use of a Sortase gene product as a purification tag. Neither of the documents upon which the Examiner bases the lack of unity objection makes any reference of the use of Sortase gene products as purification tags. Thus, the common technical feature linking each of Groups II, III and IV is novel.

US 5,804,408 relates to a method of expressing polypeptides in cells of blue-green algae, the method being characterized by the use of a structural gene comprising parts of the RuBisCO gene. The method may involve the separation and recovery of peptides from cells of the blue-green algae; however, there is no mention in this document of the use of Sortase gene products as purification tags. Likewise, Graham-Siegenthaler, which has also been cited by the Examiner as justification for the restriction requirement, makes no mention of the use of Sortase gene products, let alone their use as purification tags. This document is concerned with the production of recombinant Calpain II sub-units and describes their reconstitution but, crucially, does not refer to the use of Sortase gene products as purification tags. Accordingly, the Examiner is respectfully requested to reconsider the finding of lack of unity, at least insofar as it relates to Groups II, III and IV.

New claims 44 and 45 recite methods wherein a solubility enhancing tag comprises a SNUT tag. These claims share the same special technical feature under the terms of PCT Rule 13.1 and PCT Rule 13.2 as the inventions defined as Group II, III and IV. As clearly explained

in the application as filed, the SNUT tag is a tag derived from a Sortase gene product (see page 6, lines 24-26 of the application as filed). As the methods of the invention defined in claims 44 and 45 relate to methods of producing soluble bioactive domains of a protein of interest with a SNUT tag as a solubility enhancing tag, they share the same special technical feature as the claims of Groups II, III and IV, i.e., the use of a Sortase gene product as a solubility enhancing purification tag.

Joinder of new claims 44 and 45 with Group IV is respectfully. Furthermore, reconsideration of the lack of unity objection and resulting restriction requirement is requested, to the extent of a finding of disunity as among Groups II, III and IV. In this regard, joinder of Groups II and III with the elected Group IV is earnestly requested.

Remarks Regarding Species Election Requirement

Claims 44 and 45 are based on claims from Group I, but are limited in the recitation of a Sortase gene product as a solubility enhancing tag, specifically the Sortase gene product SNUT. Applicants believe that new claims 44 and 45 are free of the election of species requirement imposed against Group I, since the new claims are properly grouped in Group IV. However, to the extent that claims 44 and 45 may include elements of claims of Group I which have triggered an election of species requirement, Applicants state the following.

Regarding Claim 44:

Claim 44 does not recite a PCR method. Moreover, no claim dependent on claim 44 recites plural species of PCR methods from which an election may be made. Hence no election of PCR method from (a) is required.

As to the species of employed solubility enhancing tag, claim 44 already recites SNUT. Hence no election of solubility enhancing tag from (b) is required.

Neither claim 44, nor any claim dependent from claim 44, recites species of bacteria from which an election may be made. Hence no election of a bacteria from (c) is required.

Neither claim 44, nor any claim dependent from claim 44, recites a species of protein of interest from which an election may be made. Hence no election of protein of interest from (d) is required.

Regarding Claim 45:

Claim 45 does not recite a plurality of PCR conditions in the disjunctive from which an election may be made. Rather, claim 45 recites that PCT methods (i), (ii) and (iii) are run in parallel. Hence no election of PCR method species from (a) is required.

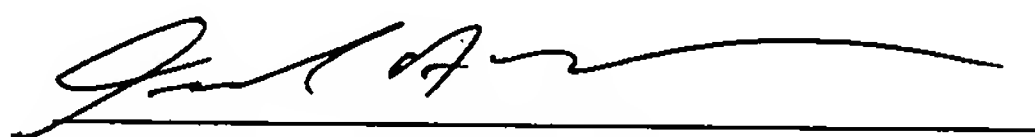
As to the species of employed solubility enhancing tag, claim 44 already recites SNUT. Hence no election of solubility enhancing tag from (b) is required.

Neither claim 45, nor any claim dependent from claim 45, recites species of bacteria from which an election may be made. Hence no election of a bacteria from (c) is required.

Neither claim 45, nor any claim dependent from claim 45, recites a species of protein of interest from which an election may be made. Hence no election of protein of interest from (d) is required.

Respectfully submitted,

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